

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL INDUSTRIES
LTD., TEVA NEUROSCIENCE, INC.
and YEDA RESEARCH AND
DEVELOPMENT CO. LTD.,

Plaintiffs,

v.

SANDOZ INC., SANDOZ
INTERNATIONAL GMBH,
NOVARTIS AG, and MOMENTA
PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 08-CV-7611 (WHP) (AJP)

TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL INDUSTRIES
LTD., TEVA NEUROSCIENCE, INC.,
and YEDA RESEARCH AND
DEVELOPMENT CO. LTD.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,
MYLAN INC., and NATCO PHARMA LTD.,

Defendants.

Civil Action No. 09-CV-8824 (WHP) (AJP)

**REPLY IN SUPPORT OF PLAINTIFFS' RULE 60(B) MOTION TO VACATE THE
MODIFICATION TO THE FINAL JUDGMENT**

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The Federal Circuit's decision is the only reason why the permanent injunction entered by Judge Jones is not in force today. The Supreme Court has now said that the Federal Circuit's decision was wrong on a foundational issue, and vacated it. That vacatur wipes the slate clean, but Defendants assert that the modified judgment remains indelible, even now that the sole legal reason for the modification is gone. Remarkably, Defendants insist that this Court must still take its rule of decision from a *vacated Federal Circuit decision* rather than a 7-2 decision from the Supreme Court. Defendants have the analysis precisely backwards. They may not continue to reap the benefit of the vacated decision until the Federal Circuit admits its error; rather, if they want to challenge the injunction, they must win their challenge to Teva's patent, this time under the correct standard. Until that happens, the status quo *before* the Federal Circuit decision should govern: Teva needs and is entitled to restoration of the injunction against infringement.

A. The Amended Judgment Is Based On The Federal Circuit Decision, And The Supreme Court Has Ruled That The Federal Circuit Decision Is Wrong.

1. As an initial matter, Defendants retreat from their previous attempts to argue that this Court lacks jurisdiction merely by virtue of the fact that the case is still pending in the Supreme Court: the Federal Circuit conferred jurisdiction on this Court by issuing its mandate, it has not recalled that mandate, and Defendants appear to acknowledge that the granting of certiorari does not divest this Court of that jurisdiction. *See* Defs.' Opp. 7; Teva Mot. 8-9.

2. The Supreme Court's decision is what allows this Court to exercise that jurisdiction, because it frees this Court of the obligation to follow the Federal Circuit's mandate. That is why Teva brought its motion only after the Supreme Court ruled: an appellate court's mandate is no longer binding "where an intervening decision has changed the law." *Yankee Atomic Elec. Co. v. United States*, 679 F.3d 1354, 1360 (Fed. Cir. 2012); *accord City of Pontiac Gen. Emps.' Ret. Sys. v. MBIA, Inc.*, 637 F.3d 169, 173 (2d Cir. 2011).

Defendants argue that this Court should continue to treat the Federal Circuit’s previous judgment as if it were good law, rather than demonstrably erroneous. And although they spend considerable time on whether the Supreme Court has issued the certified copy of its judgment, that turns out to be just a red herring—Defendants contend that this Court can take no action *even after* the Supreme Court’s judgment issues, but must wait for *the Federal Circuit* to change its own decision. Defs.’ Opp. 1, 12. Defendants are wrong in both respects: they can no longer reap the benefit of the erroneous Federal Circuit decision, not even for 25 days. This Court certainly need not wait for the Federal Circuit to acknowledge its previous error expressly.

The Supreme Court’s decision became the law the day it was issued. The Federal Circuit is already citing it¹—just as courts around the country follow Supreme Court decisions as of the day they are issued. *E.g.*, *United States v. Booker*, 543 U.S. 220, 228 (2005) (sentencing court applied the Supreme Court’s decision in *Blakely v. Washington* only “[a] few days after” that decision); *Hotte v. United States*, 174 F. App’x 595, 596 (2d Cir. 2006) (defendant was entitled to the benefit of the Supreme Court’s decision in *Apprendi v. New Jersey* because his conviction became final three days after that decision—well before the judgment issued). The Supreme Court itself has ordered other cases remanded based on its decision in this case. *See, e.g.*, *Lighting Ballast Control LLC v. Universal Lighting Techs., Inc.*, ___ S. Ct. ___, 2015 WL 303220 (Jan. 26, 2015) (mem.). If that decision is binding on every other litigant in this country, it is binding on the parties here, unless it is reheard—and Defendants have confirmed that they will not seek rehearing.

Defendants attempt to draw support from a few words of *dictum* in *United States v. Chiarella*, 214 F.2d 838, 839 (2d Cir. 1954), but as Teva pointed out in its Motion (at 10 n.4),

¹ *See, e.g.*, *In re Papst Licensing Digital Camera Patent Litig.*, No. 2014-1110, 2015 WL 408127, at *3 (Fed. Cir. Feb. 2, 2015).

there is no indication that the court of appeals in that case ever issued its mandate to the district court. If the Second Circuit had issued its mandate before the case went to the Supreme Court, Chiarella would have been resentenced in 1951. Defendants offer no response to that point. In this case, the Federal Circuit handed jurisdiction back to this Court in November 2013.²

For exactly that reason, it is this Court, not the Supreme Court, that should act. This Court amended the permanent injunction, based on the Federal Circuit's mandate. This Court is the one to undo the amendment. Defendants fail to show that the Supreme Court or a Justice even *could* permanently undo such an order (as opposed to stay it pending appeal).

3. Even if there were some reason why this Court may not grant relief *today*, Defendants give no valid reason why this Court would not be permitted to make its action effective once the Supreme Court's certified judgment *does* issue, or at least to issue an indicative ruling under Rule 62.1. Indeed, once the Supreme Court closes the case but before the Federal Circuit reassumes jurisdiction—a process that may take days or weeks³—this Court will indisputably be the *only* court with the power to grant Teva the relief it seeks.

Defendants advance the remarkable proposition that this Court should continue acting “in accordance with the [Federal] Circuit's original mandate” *even after the Federal Circuit's decision is vacated and the mandate recalled*, unless and until the Federal Circuit changes the

² Defendants also cite *Whitfield v. United States*, No. 8:06-CV-366-T-27TBM, 2009 WL 2150965, at *1–*2 (M.D. Fla. July 13, 2009), which is even less relevant. *Whitfield* held that, in calculating the time to seek postconviction review, “the date on which the judgment of conviction becomes final” includes the time spent *actually seeking* rehearing in the Supreme Court. That statutory-interpretation question sheds no light on when the Supreme Court's decision became binding, and in any event the court did not hold that finality includes the 25-day rehearing period when no one seeks rehearing.

³ See, e.g., *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 571 F. App'x 958 (Fed. Cir. 2014) (mandate recalled 17 days after Supreme Court's certified judgment); Case Docket Sheet, *Bormes v. United States*, No. 09-1546 (Fed. Cir.), ECF No. 7 (mandate recalled 22 days after Supreme Court's certified judgment).

prior panel decision. Defs.’ Opp. 12; *see id.* at 6. Defendants acknowledge, as they must, that this Court could do no such thing if the Supreme Court had *reversed* the Federal Circuit. But Defendants contend, without any support, that this case is different because the Supreme Court instead “vacated.” *Id.* at 15. Defendants cannot turn a vacatur into an affirmance. The Supreme Court determined that the Federal Circuit had gone about the appeal incorrectly and vacated the panel decision so that the Federal Circuit could redo the appeal under the correct standard of review. The law is clear: the vacated decision can no longer enjoy *either* “precedential effect” or “law of the case” status. *O’Connor v. Donaldson*, 422 U.S. 563, 577 n.12 (1975).

Vacatur “wip[es] the slate clean.” *In re Freeport Italian Bakery, Inc.*, 340 F.2d 50, 55 (2d Cir. 1965); *accord, e.g., United States v. Whitmore*, 573 F. App’x 24, 26 (2d Cir. 2014) (vacating sentence so that re-sentencing may be “conducted on a blank slate”); *Cornwall v. U.S. Constr. Mfg., Inc.*, 800 F.2d 250, 254 (Fed. Cir. 1986) (on vacatur, “[t]he slate is literally wiped clean”) (citation omitted)). The effect of “vacating the judgment” is to “restor[e] the action to the *status quo ante*” in the court from which it came. *Golden Buddha Corp. v. Canadian Land Co. of Am., N.V.*, 931 F.2d 196, 202 (2d Cir. 1991).

Here the *status quo ante* means the way matters stood *before* the Federal Circuit issued the now-vacated panel decision: Defendants’ invalidity claim failed, and this Court enjoined them from infringing the patent. Defendants, however, repeatedly insist that the Court should preserve today’s *status quo*—essentially keeping the vacated decision in effect—rather than restore the *status quo ante*. But that would deprive the Supreme Court’s judgment of any effect, unless and until the Federal Circuit chooses to take some action based on that judgment. There is no support for the notion that the Supreme Court’s judgments lack force until an appeals court

implements them.⁴ And the Court should not continue relying on “an earlier judgment that has been reversed or vacated” merely because the Federal Circuit *might* someday reach the same conclusion. *See, e.g., Pac. & S. Co. v. Duncan*, No. CIV. C81-1106-ODE, 1991 WL 279410, at *1 (N.D. Ga. Dec. 5, 1991) (reinstating a permanent injunction when the previously-controlling appellate decision was vacated upon granting of rehearing en banc, even though the en banc court might have later reached the same conclusion as the panel).

B. Rule 62(c) Does Not Apply Because Teva Is Seeking Restoration Of Its Permanent Injunction, Not A New, Temporary Injunction Pending Appeal.

Much of Defendants’ argument depends on mischaracterizing the relief Teva seeks as an injunction pending appeal. To the contrary, Teva has made clear that it seeks restoration of the *permanent* injunction that it won after a full trial before Judge Jones. That injunction is a remedy for infringement that lasts for the life of the patent, whether there is any appeal or not.

An injunction pending appeal is a remedy sought by the losing litigant in district court, who wants to keep the winner from acting on his victory until after the loser has a chance to pursue relief on appeal. When the appeal ends, so does the injunction pending appeal.

But Teva is not a losing litigant. Teva *won* in this Court. And the injunction it obtained—and now seeks to restore—is not in any way dependent on the appeal that *Defendants* are pursuing to the Federal Circuit. If Defendants dismissed their appeals, it would be perfectly clear that Teva’s victory remained intact. That is why Teva’s injunction is a *permanent* injunction.

Suppose this were a criminal case. The District Court enters a judgment of conviction and sentence. There is no bail pending appeal. The defendant starts serving his sentence. The

⁴ In *Medimmune, Inc. v. Genentech, Inc.*, 219 F. App’x 986 (Fed. Cir. 2007) (cited at Defs.’ Opp. 9-10), unlike here, nothing had happened in reliance on the Federal Circuit’s mandate, so there was no interim action to undo based on the Supreme Court ruling.

Court of Appeals reverses, ordering a judgment of acquittal. The court issues its mandate, and the defendant is duly released. Then the Supreme Court vacates and remands to the Court of Appeals to consider the defendant's appeal under the proper standard. Once the Court of Appeals' judgment has been set aside, must the government seek some kind of extra injunction pending appeal before it may return the defendant to custody? No. The controlling judgment is the District Court's judgment of *conviction*. The vacatur of the Court of Appeals' judgment justifies returning the defendant to custody, unless and until the conviction is set aside again, this time under the proper standard. Perhaps the defendant now has a good argument that he is likely to win on (the new) appeal, and perhaps he may seek bail on that basis. But it will be the defendant's burden, as the *appellant* seeking to upset a judgment, to seek that interim relief.

So too here. The Supreme Court has put Defendants back in the position of being *appellants*—challenging the judgment against them. To win permanent relief, they must prevail on appeal. And to win interim relief, they must satisfy the well-established standard for seeking a stay of an injunction. They have not made any such showing.⁵

C. No Developments Since The Federal Circuit Ruling Prevent This Court From Correcting The Judgment.

Defendants repeatedly contend that the judgment *cannot* be restored to the status quo ante, and a new injunction is necessary—because the *amended* injunction has expired, or because some of the patents have expired, or because Teva supposedly did not object to the entry of the amended judgment. None of these arguments carries any weight.

First, the expiration of the *amended* injunction says nothing about whether the *original* injunction may be reinstated. *That* injunction would remain in force today if it had not been

⁵ Defendants briefly assert (Defs.' Opp. 13) that Rule 60(b)(5) cannot be used by a *plaintiff* seeking to reopen a judgment to reinstate a claim or remedy—only by a defendant. That is patently incorrect. *E.g., In re Jones*, 670 F.3d 265, 267-68 (D.C. Cir. 2012).

erroneously amended and shortened based on the court of appeals' mandate. And "compliance with the Court of Appeals' mandate does not moot the issue of the correctness of the court's decision." *Norfolk & W. Ry. Co. v. Am. Train Dispatchers Ass'n*, 499 U.S. 117, 128 n.3 (1991). If that were enough to end the dispute, this case (and every other case in which a stay of mandate is denied) would have been mooted before it even got to the Supreme Court.

Nor is there any need to change the injunction in light of the expiration of other patents. All of the relevant patent expiration dates are incorporated into the injunction. *See, e.g.*, ECF No. 338, ¶¶ 11-12. The injunction can therefore be reinstated verbatim. And if some modification were warranted, the burden would be on Defendants to show why. *Teva* Mot. 17.

Defendants cannot seriously argue that Teva had to oppose the implementation of the Federal Circuit's mandate or else be stuck with that mandate indefinitely. Not only was such resistance not required, it would have been futile and perhaps even sanctionable, *see Virgin Atl. Airways, Ltd. v. Nat'l Mediation Bd.*, 956 F.2d 1245, 1254-55 (2d Cir. 1992). The stipulation that the parties presented to the Court recited that the amendment faithfully implemented the Federal Circuit's mandate. ECF No. 352, at 2 (Teva "do[es] not oppose this motion, as the form of judgment accurately reflects the mandate from the Federal Circuit."). Nothing more was needed to preserve Teva's position. *See In re Papst*, ___ F.3d ___, 2015 WL 408127, at *9.

D. This Court Has Undisputed Power To Issue An Indicative Ruling.

Defendants offer no argument that this Court *cannot* issue an indicative ruling pursuant to Rule 62.1. Nor could they: the plain text of the Rule eliminates any jurisdictional obstacle based on the pendency of an appeal. Instead, Defendants contend that Rule 62.1 should not apply because Teva is really seeking an injunction pending appeal. That contention is debunked above.

Nor is Teva asking this Court to adjudicate "the same question being reviewed by the court of appeals." *Defs.' Opp.* 16 (quoting *Ret. Bd. of Policemen's Annuity & Ben. Fund v. Bank*

of *N.Y. Mellon*, 297 F.R.D. 218, 221 (S.D.N.Y. 2013)). Defendants' appeal presents the question whether the patent is indefinite and the July 2012 judgment should be reversed. This motion does not remotely ask this Court to decide that question. Rather, it asks the Court to decide the legal status of the *amended* judgment entered in December 2013—a judgment from which Defendants are not appealing.

An indicative ruling would bring jurisdictional skirmishing to an end and provide an answer as to whether Teva is, or is not, entitled to get its injunction back at this time. And that procedure need not delay the briefing on appeal. Accordingly, if the Court is in any doubt about its jurisdiction, it should nonetheless provide a proposed answer on the merits under Rule 62.1.

E. Defendants Misstate Their Chances Of Success.

Judge Jones awarded Teva the permanent injunction as a remedy for infringement. Defendants never challenged that remedy, and they clearly are barred from challenging the propriety of that form of relief at this late date (except to the extent they can persuade the Federal Circuit that the underlying patent is invalid). And to the extent they contend things have changed—their own chances on appeal, or the balance of the harms⁶—those considerations belong in a motion to stay or modify the injunction once it is restored.

1. Defendants emphasize that an injunction is not automatic in a patent-infringement case. Indeed it is not—which means that Defendants' decision not to contest the propriety of injunctive relief was a conscious, considered one. The Federal Circuit has squarely held that when a patent defendant appeals, but does *not* challenge the award of an injunctive remedy, that defendant can no longer argue that the remedy was wrong *ab initio*. See *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1359-60 (Fed. Cir. 2008). That applies with double force here: the July

⁶ At present Defendants' claim of harm appears to be as speculative as it ever was: no Defendant yet has FDA approval to market an infringing product. Teva Mot. 5.

2012 stipulated judgment specifically provides that Defendants do not waive the right to appeal, “including the injunctive relief granted,” but only “to the extent the Court’s findings or holdings are modified on appeal.” ECF No. 338, ¶ 14. If the patent’s validity is affirmed on appeal, Defendants have no room to dispute the injunctive remedy.

For that reason among others, Defendants’ reliance on the Chief Justice’s denial of a *stay of mandate* (not a permanent injunction) is misplaced. As the Chief Justice has explained, the irreparable-harm calculus for a form of *interim* relief, such as a stay, turns on “‘prevent[ing] irreparable injury . . . ’ *pending review*.” *Nken v. Holder*, 556 U.S. 418, 432 (2009) (Roberts, C.J.) (citation omitted; emphasis added). Whether Teva would suffer harm during the pendency of Supreme Court review does not speak to whether Teva would suffer harm during the life of the patent. And as in *Amado*, Defendants cannot relitigate the latter question.

2. Defendants repeatedly assert that they are likely to win on appeal, and that Teva should be denied its injunction for that reason. It bears noting that Defendants made the exact same argument—that changing the standard of review should not affect the outcome of this case—to argue that the Supreme Court should not take the case. Resp. Cert. Br. 19-21, *available at* <http://bit.ly/1Ko0E0t>. The Court granted certiorari nonetheless. On the merits, Defendants argued that the case should not be remanded even if the standard of review were changed, Resp. Merits Br. 42-65, *available at* <http://bit.ly/1Ko0Gp6>, but the Court remanded nonetheless.

To the contrary, the Supreme Court’s opinion serves to refute an important aspect of Defendants’ argument. Defendants insist that *de novo* review is appropriate because the interpretive question turns on words “intrinsic” to the patent. But that misses the point. The Supreme Court held that the correct understanding of Figure 1—which is *also* intrinsic to the patent—presents a question of fact. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831,

842-43 (2015). Judge Jones made numerous factual findings based on *extrinsic* evidence, findings that bear heavily on the interpretation of both the patent and its prosecution history. 810 F. Supp. 2d 578, 588-90, 591-92 (S.D.N.Y. 2011); Pet. Merits Br. 13-14, *available at* <http://bit.ly/1KyTbd9>. It is those factual findings, which Defendants never mention, that are entitled to deference on appeal. And it is that form of deference that makes Defendants unlikely to prevail under any standard of indefiniteness.

F. Defendants' Demand For A Bond Shows That Defendants Can Be Protected Without Depriving Teva Of Its Injunction.

Defendants insist that Teva should post a bond if the injunction is restored. No bond was required from Teva when judgment was entered in July 2012, for the simple reason that appeals from *permanent* injunctions (unlike interim relief) do not require a bond. If no bond was required when the injunction issued, none should be needed when it re-issues.

Nevertheless, Teva is prepared to post a bond if the Court thinks it advisable. As Defendants suggest, the actual amount of any bond is properly a subject for separate briefing or negotiation. Accordingly, the Court should enter the injunction now and, if need be, order briefing on the need for and size of any bond.

CONCLUSION

For the foregoing reasons, and those stated in its opening brief, Teva respectfully requests that the Court vacate the modification to the final judgment.

Dated: February 6, 2015

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on February 6, 2015.

/s/ Elizabeth J. Holland